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| EXAMINER |
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BRUENJES, CHRISTOPHER P

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| ART UNIT | PAPER NUMBER |
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1772

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/06/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/667,710

Applicant(s)

BAVARO ET AL.

Examiner

Christopher P. Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

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at the time the application was filed, had possession of the claimed invention.

The limitation "a minority of the volume of the marker is metal solids and a majority of the volume of the marker is nonmetal" does not appear to have support in the originally filed application. The specification provides that the particles are selected from a large collection of different metals and does not teach that only one metal should be selected. Furthermore, the example pointed to in the specification for support only teaches a ratio of tungsten to polymer in the combination blend. This does not describe to one having ordinary skill in the art that tungsten is the only metal present in the marker; it merely provides the ratio between two elements of the blend without defining whether other elements are included. Furthermore, there does not appear to be support in the originally filed application for the limitation that there be a minority of the volume of the marker formed from metal solids. Minority leads one to believe any amount less than 50% and there doesn't appear to be any support for a cap on the volume of metal in the marker at less than 50%.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al (USPN 5,776,141) in view of Elliott (US 2003/0164063).

Regarding claims 1 and 4-5, Klein et al teach a radio marker for an intraluminal medical device comprising a polymer and radiopaque particles (col.11, 1.15-30). The polymer is a polyether block amide copolymer and said radiopaque particles

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comprise tungsten powder, which is loaded approximately 36 volume percent of said marker since it is 90% by weight (col.11, 1.22-26). The blend of the polymer and the radiopaque particles forms a highly radiopaque yet relatively flexible radiopaque marker configured for securing to the intraluminal medical device and the radiopaque particles (col.11, 1.15-30) The marker is formed with a minority of the volume metal solids and the majority of volume nonmetal.

Klein et al fail to teach adding a wetting agent for facilitating encapsulation of said particle by said polymer and the diameter of the particles. However, Elliott teaches that to improve the packing density of tungsten powder the powder is milled to deagglomerate the fine particle clusters. To get higher packing densities such as 36 volume percent, Elliott teaches the mean particle size is between 1 and 10 microns (p.2, paragraph 43). Elliott further teaches specific examples wherein when the median particle diameter is about 10 microns, the 90% of the particles have a diameter less than 18.5 microns (p.6, paragraph 94). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that when the mean particle size is within the range of 1 and 10 microns the maximum diameter of a particle would be about 20 microns.

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Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiopaque particles of Klein et al with a mean diameter of at least 2 microns and a maximum diameter of about 20 microns in order to maximize the packing density and ultimately be able to form a combination with 36 volume percent radiopaque particles, as taught by Elliott.

Furthermore, Elliott teaches that a wetting agent such as maleic anhydride graft polyolefin is blended with the polymer forming the radiopaque particle containing article as a strength enhancing agent (p.5, paragraph 92). Therefore, it would have been obvious to one having ordinary skill in the art to add maleic anhydride graft polyolefin to a tungsten and polymer mixture in order to enhance the strength of the mixture, as taught by Elliott.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a maleic anhydride graft polyolefin to the radiopaque marker of Klein et al in order to enhance the strength of the mixture, as taught by Elliott.

Regarding claims 6-8, the limitations that the particles are produced by a pusher process or by an atomization process are given little patentable weight in an article claim.

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Although all limitations are considered, process limitations in an article claim are only given weight insofar as the structural differences the process teaches. In this case, because the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94), the structural differences provided by the processes of forming particles that are substantially equiaxed are taught by Elliott.

Regarding claim 9, it is well known in the art that antioxidants are added to elastomers in order to prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation. Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the marker of Klein et al, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claim 10, Pebax is thermoplastic.

Regarding claim 11, Klein et al teach the marker has a ring shape with is a tubular structure.

Response to Arguments

7. Applicant's arguments regarding the 35 U.S.C. 112 rejections of claims 1-11 have been fully considered but they are not persuasive.

Although it is agreed the previous limitations rejected as not being supported by the original disclosure have been deleted rendering the previous 112 first paragraph rejection moot, a new rejection has been made above because the newly added limitations to claim 1 are also not supported in the original disclosure.

8. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 1-11 have been fully considered but they are not persuasive.

Regarding applicant's argument that if Klein et al is modified by Elliott, the 80-90% tungsten in polymeric material marker of Klein would be replaced with the tungsten, second metal, binder composition of Elliott. Although the ultimate goal of Elliott might be to produce replacement for lead shot using a blend of tungsten and a second metal in a binder, Elliott teaches generally, that to increase packing density of tungsten powder the powder is milled to deagglomerate the fine particle clusters which leads to a mean particle size between 1-

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10 microns and a sample distribution with 90% of particles being less than 18.5 microns. Therefore, Elliott does not teach one having ordinary skill in the art at the time applicant's invention was made that to increase the packing density of tungsten powder in a binder you have to add a second metal powder.

Furthermore, even if the teachings of Klein et al and Elliott did require the second metal in the composite, the addition of a second metal according to Elliott does not require that the metal for a majority by volume of the marker. Specifically, Elliott teaches the tungsten in the range of 80-99% by weight and the other metal in a range of 2-15% by weight. The amount of each would be determined based on the intended end use of marker and many of the combinations would maintain a minority volume percentage in the marker. Also Elliott teaches examples with greater than 55 volume percent metals but does not teach that the volume percent of metals is required to be that high, merely that it is possible.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489.

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The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
February 26, 2007


ALICIA CHEVALIER
PRIMARY EXAMINER